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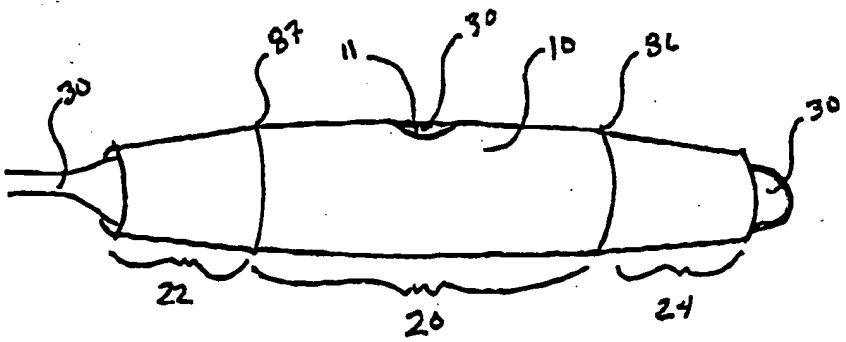
(54) Title: DIFFERENTIALLY EXPANDING STENT AND METHODS OF USE



(57) Abstract: A stent (10) for placement in a body lumen comprises multiple sections (20, 22, 24). Each of the sections expand at a particular pressure or at a rate in the absence of a constraining pressure. Thus, a predetermind sequence of expansion is provided across the stent.

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DIFFERENTIALLY EXPANDING STENT AND METHODS OF USE

This application claims the benefit of U.S. Provisional Application No. 60/155,611 filed on September 23, 1999, the complete disclosure of which is incorporated herein by reference.

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is being filed concurrently with related U.S. Patent App. Serial No. _____ (Attorney Docket Number 019601-000420), entitled "Stent Range Transducers and Methods of Use"; and U.S. Patent App. Serial No. _____ (Attorney Docket Number 019601-000430), entitled "Bifurcation Stent Systems and Methods", the complete disclosures of which are incorporated herein by reference and filed at a date even herewith.

TECHNICAL FIELD

The present invention relates to stents, stent systems and methods for delivery and use thereof.

BACKGROUND OF THE INVENTION

A type of endoprosthesis device, commonly referred to as a stent, may be placed or implanted within a vein, artery or other hollow body organ or lumen for treating occlusions, stenoses, or aneurysms of a vessel by reinforcing the wall of the vessel or by expanding the vessel. Stents have been used to treat dissections in blood vessel walls caused by balloon angioplasty of the coronary arteries as well as peripheral arteries and to improve angioplasty results by preventing elastic recoil and remodeling of the vessel wall. Two randomized multicenter trials have recently shown a lower restenosis rate in stent treated coronary arteries compared with balloon angioplasty alone (*Serruys, PW et al.*, New England Journal of Medicine 331: 489-495 (1994) and *Fischman, DL et al.* New England Journal of Medicine 331:496-501 (1994)). Stents have been successfully implanted in the urinary tract, the bile duct, the esophagus and the tracheo-bronchial tree to reinforce those body organs, as well as implanted into the neurovascular, peripheral

vascular, coronary, cardiac, and renal systems, among others. The term "stent" as used in this Application is a device which is intraluminally implanted within bodily vessels to reinforce collapsing, dissected, partially occluded, weakened, diseased or abnormally dilated or small segments of a vessel wall.

One of the drawbacks of conventional stents is that they are difficult to position. In general, positioning a stent involves moving the stent to the desired position and then maintaining the position while the stent is deployed. Accurate positioning is critical to proper operation of the stent. For example, the use of such stents to treat diseased vessels at or near a bifurcation (branch point) of a vessel requires very accurate positioning otherwise, there is a potential for compromising the degree of patency of the main vessel and/or its branches, or the bifurcation point. Compromising the bifurcation point limits the ability to insert a branch stent into the side branch if the result of treatment of the main vessel is suboptimal. Suboptimal results may occur as a result of several mechanisms, such as displacing diseased tissue, plaque shifting, vessel spasm, dissection with or without intimal flaps, thrombosis, and embolism.

In light of the foregoing, it would be desirable to provide methods and/or apparatus to increase positioning accuracy and to control tissue displacement.

SUMMARY OF THE INVENTION

The invention provides methods and apparatus for ensuring accurate positioning of a stent in a body lumen. In one aspect, the invention provides for accurate positioning of a stent near a vessel bifurcation such that a side hole in the stent aligns with the ostium of a branch vessel. The invention also provides techniques for accurately positioning a stent near a critical area of a body lumen, such as a diseased portion of a vessel wall.

In one particular embodiment, a stent comprises an expandable tubular wall comprising first and second portions. The first portion comprises a first makeup with a corresponding expansion factor and the second portion comprises a second makeup with a corresponding expansion factor.

In some embodiments, the first and second makeups provide a predetermined sequence of expansion for the stent. In an embodiment, the predetermined sequence includes expansion of the first portion prior to the second portion.

In some embodiments, the first makeup is a material formed into a particular geometry. For example, the geometry may include a zigzag geometry, an S-curve geometry, an undulating geometry, and the like. In an embodiment, the geometry of the first makeup is a zigzag geometry while the geometry of the second makeup is an S-curve geometry.

In some embodiments, an expander is at least partially disposed within an area defined by the expandable tubular wall of the stent. The expander is operable to apply pressure on the expandable tubular wall. In an embodiment, the expander is a balloon.

In yet other embodiments, the stent further comprises a third portion adjacent to the first portion and spaced apart from the second portion. The third portion has the second makeup such that the second and third portions have about the same expansion factor. In an embodiment, the first portion expands more rapidly than the second and third portions when the first, second and third portions are subjected to a steadily increasing pressure. In one embodiment, the increasing pressure is an increasing radial pressure.

The present invention also provides methods for deploying the stent in a body lumen. In one embodiment, a method comprises providing a stent including a tubular wall. The tubular wall comprises both a first and second portion. The first portion is adapted to expand in response to a first pressure, and the second portion is adapted to expand in response to a second pressure. The stent is positioned in the body lumen. The tubular wall is subjected to a first pressure, wherein the first portion expands more than the second portion. The tubular wall is then subjected to a second pressure greater than the first pressure, to fully expand the stent.

In some aspects, the stent includes a side hole, and positioning the stent includes positioning the side hole adjacent to a bifurcation in the body lumen. In one aspect, an expander is provided for subjecting the tubular wall to a desired pressure.

Reference to the remaining portions of the specification, including the drawings and claims, will realize other features and advantages of the present invention. Further features and advantages of the present invention, as well as the structure and operation of various embodiments of the present invention, are described in detail below with respect to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an overall view of a stent according to an embodiment of the present invention, the stent illustrated in a collapsed orientation;

Figs. 2A, 3A and 4A depict overall views of a portion of individual struts for use in the present invention;

Fig. 2B, 3B and 4B illustrate patterns of struts made up of the struts shown in Figs. 2A, 3A and 4A, respectively, used to form a portion of the stent shown in Fig. 1;

Fig. 5 illustrates an interface between strut patterns forming a portion of the stent illustrated in Fig. 1;

Fig. 6 depicts an overall view of the stent of Fig. 1 in a partially deployed orientation;

Fig. 7 depicts an overall view of the stent of Fig. 1 in a fully deployed orientation;

Fig. 8 depicts an overall view of a stent according to an alternative embodiment of the present invention; and

Fig. 9 shows a kit including a stent and instructions for use according to the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides methods and apparatus for maintaining stent position during deployment. The methods and apparatus may be used to assure alignment of a side hole in a stent with the ostium of a branch vessel. Further, the methods and apparatus may be used to control cell distribution during stent deployment.

Applications of the invention include use in relation to hollow organs or body lumens including, among others, the cardiac, coronary, carotid artery, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain. In a typical use, a stent according to the present invention is positioned within a body lumen and subsequently deployed.

Upon deployment, the stent is expanded to where it contacts, and even supports or expands the body lumen such as a vascular wall. As the stent contacts the wall, it causes cells of the wall to re-distribute at the contact point. For example, when the stent is expanded, the vascular wall may stretch, causing cell density in the stretched

area to decrease. Alternatively, both ends of the stent can expand more rapidly than a midsection resulting in a higher cell density near the midsection than would be achieved if all portions of the stent expanded simultaneously. Thus, the present invention advantageously provides for control of cell re-distribution during stent deployment. This control may result in more uniform and even distribution of cell structure.

In addition, during stent deployment, the stent often shifts position as it contacts the body lumen, such as the vascular wall. For example, during deployment a stent may first contact the body lumen wall at the distal end of the stent. This contact can push the stent such that the position of the stent midsection shifts from a pre-deployment position. This stent shift is inimical to proper stent positioning.

In one application, a stent must be positioned in a vessel near a bifurcation such that a side hole in the stent midsection aligns with an ostium of a branch vessel. As described, stent shift can cause the stent midsection to shift which would cause a misalignment between the side hole and the ostium. This misalignment can reduce the patency or even occlude the ostium. To avoid this scenario, the invention provides for a stent which expands more rapidly at the midsection than at the proximal and distal ends. This differential expansion causes the stent to initially contact the vessel at the vessel bifurcation. By initially contacting the vessel at the bifurcation, the magnitude of stent shift relative to the bifurcation is significantly reduced and the side hole and ostium remain aligned.

According to the invention, stents can be designed to sequentially deploy such that any number of lumen areas, or critical portions, are contacted first or in a prescribed sequence. Accordingly, other advantages of the invention include, but are not limited to, providing contact with a lesion or diseased area prior to contact with surrounding healthy areas during stent deployment. Alternatively, initial contact with healthy areas followed by contact with diseased areas can be provided during stent deployment.

As should be noted, the differential stent according to the present invention can be applied in a number of ways. Depending upon the lesion, calcification, vessel narrowing, vessel morphology, and other considerations, the stent may be comprised of any number of sections that expand at different rates. Further, expansion of a stent according to the present invention can be differential and/or multi-directional. Multi-directional stent expansion minimizes foreshortening of the stent.

Referring now to Fig. 1, one embodiment of stent 10 according to the present invention will be described. Stent 10 includes a midsection 20, a proximal portion 22, and a distal portion 24. A distal interface 86 exists at a junction of distal portion 24 and midsection 20, and a proximal interface 87 exists at a junction of proximal portion 22 and midsection 20. It will be appreciated by those skilled in the art that the relative sizes of distal portion 24, midsection 20 and proximal portion 22 may vary within the scope of the present invention from that shown. Further, interfaces 86 and 87 may have a non-linear or other configuration than shown.

Midsection 20 includes a side hole 11. As described herein, side hole 11 refers to a relatively large hole which is intended to be aligned with the ostium of a branch vessel. Side hole 11 is separate from, and larger than, any of the multiple passageways extending through the side of stent 10 between struts in the stent geometry. In some embodiments, side hole 11 is defined by a band of continuous material which defines the perimeter of side hole 11. This continuous band of material preferably comprises discontinuities over its length so that the area of side hole 11 expands together with the expansion of stent 10. In various aspects, the continuous band comprises protrusions which project inwardly from a peripheral edge of side hole 11. Preferably, these protrusions (or expandable portions) are initially aligned within a cylindrical envelope of the tubular body of stent 10.

In another embodiment, stent 10, is formed without side hole 11. For example, in applications not involving vessel bifurcations, such as reducing vessel narrowing away from a bifurcation, side hole 11 is unnecessary, or undesirable. In these applications, stent 10 is provided without side hole 11.

A makeup of midsection 20, proximal portion 22, and distal portion 24 includes a plurality of struts formed in particular geometries and/or with particular materials. A combination of geometry and material can be chosen to produced a desired expansion factor. The expansion factor includes a propensity to expand when a particular pressure is applied to the strut. In another embodiment, the expansion factor includes a proclivity to expand where no pressure is applied to the strut, such as when stent 10 is released from a sheath.

By choosing the geometry and material for each of midsection 20, proximal portion 22, and distal portion 24, stent 10 is designed to expand in a predetermined sequence during deployment. For example, distal portion 24 can expand before or simultaneous with proximal portion 22, which in turn can expand before

midsection 20. This predetermined expansion sequence can occur, for example, under application of a steadily increasing pressure. Any apparatus capable of applying a generally equal pressure to midsection 20, proximal portion 24 and distal portion 22 can be used. In some embodiments, the apparatus for applying pressure is a balloon 30. In another embodiment, stent 10 expands differentially when released from a sheath or other restraining device. In this manner, stent 10 expansion factors control the differential expansion of stent portions 20, 22 and 24.

Delivery of stent 10 within a body lumen and deployment of stent 10 are further described in U. S. Application Serial No. _____ (Attorney Docket No. 19601-000320), entitled "Catheter with Side Sheath and Methods", filed September 15, 2000, assigned to the assignee of the present invention and incorporated herein by reference for all purposes. For example, the referenced application contains details related to aligning stent side holes with ostium of branch vessels. The methods and embodiments provided can be used in accordance with the present invention.

For example, the stent delivery system according to the present invention may employ a moveable or non-moveable side sheath or side member as further described in U.S. App. Serial No. _____ (Attorney Docket No. 19601-000320), the complete disclosure of which has been previously incorporated by reference. Additionally, for illustration, one embodiment of the referenced application provides an embodiment where a catheter system facilitates placement of the stent within the main vessel, with the side hole being in registry with an ostium of a branch vessel. This placement may be accomplished, for example, by advancing a main vessel guidewire in the main vessel until passing the branch vessel. The catheter is then advanced over the main vessel guidewire until the stent reaches or is proximal to the branch vessel. At this point, a branch vessel guidewire may be introduced through the branch vessel lumen of the catheter. The branch vessel guidewire is advanced out of the catheter and into the branch vessel to assist in aligning the side hole with the ostium of the branch vessel prior to deployment of the stent in the main vessel. To assist in guiding the branch vessel guidewire into the branch vessel, the catheter may taper at a point to a narrow distal end, which may also be curved slightly outwardly. One advantage of such a catheter system is that a single guidewire may be used to introduce the catheter. Once introduced, the catheter serves as a guide for the branch vessel guidewire.

Alignment of the side hole with the ostium can be accomplished in a variety of ways. For example, introduction of the branch vessel guidewire into the branch

vessel may sufficiently align the side hole with the ostium. Other alignment techniques may depend on the configuration of the catheter. For example, in some cases the catheter may comprise a flexible sheath that is movably coupled to the catheter body, e.g., by passing through a lumen of a truncated connector that is coupled to the catheter body. Once the branch vessel guidewire is advanced into the branch vessel, the sheath may be advanced into the branch vessel to move the side hole into registry with the ostium.

In some embodiments, struts are comprised of geometries of varying lengths, widths, and shape. Shapes can include, but are not limited to, angled, hook shaped, or S-curved shapes. Additionally, geometries can include differing densities of struts per surface area. Materials used to form the struts can include, but are not limited to, stainles steel, Nitinol, and the like.

Figs. 2B, 3B and 4B illustrate strut embodiments in accordance with the present invention. The strut geometries illustrated in Figs. 2B, 3B and 4B expand at a predetermined pressure. While these Figs. show exemplary embodiments of strut geometries, it should be recognized that many geometries are possible in accordance with the present invention. For example, alternative geometries can include struts which expand only at a particular pressure, which expand at a rate related to a particular pressure, or which expand at a particular rate without application of pressure.

Referring to Fig. 2A, an embodiment of a strut 55 according to the present invention is shown. In one embodiment, strut 55 is adapted to expand when subjected to a pressure that is about four (4) atmospheres (ATM). The geometry and material of strut 55 includes a rectangular-shaped filament 59, with dimensions 58 of about 0.004 inches by 0.005 inches, and made of stainless steel. Filament 59 is formed in a zigzag pattern with a length 56 and a curve 57. In one embodiment, length 56 is about 0.04 inches and the radius of curvature of curve 57 is about 0.005 inches. It will be appreciated by those skilled in the art that the pressure at which strut 55 expands will depend, in part, on the geometry, thickness and materials of strut 55. For example, in other embodiments, geometry, thickness and materials of strut 55 are adjusted so that strut 55 expands at between two (2) and eight (8) ATM. It should be appreciated by one skilled in the art that other expansion presures are also possible. Fig. 2B illustrates an embodiment of a structure portion 50 formed by combining a plurality of struts 55.

Referring to Fig. 3A, an embodiment of a strut 65 according to the present invention is shown. In one embodiment, strut 65 is adapted to expand when subjected to a pressure that is about three (3) ATM. The geometry and material of strut 65 includes a

rectangular-shaped filament 69 with dimensions 68 of about 0.004 inches by 0.005 inches, and made of stainless steel. Filament 69 is formed in an S-curved pattern with a length 66 and a curve 67. In one embodiment, length 66 is about 0.050 inches and curve 67 has a radius of curvature of about 0.005 inches. It will be appreciated by those skilled in the art that the pressure at which strut 65 expands will depend, in part, on the geometry, thickness and materials of strut 65. For example, in other embodiments, geometry, thickness and materials of strut 65 are adjusted so that strut 65 expands at between two (2) and eight (8) ATM. It should be appreciated by one skilled in the art that other expansion presures are also possible. Fig. 3B illustrates an embodiment of a structure portion 60 formed by combining a number of the struts 65.

Referring to Fig. 4A, an embodiment of a strut 75 according to the present invention is shown. In one embodiment, strut 75 is adapted to expand when subjected to a pressure that is about five (5) ATM. The geometry and material of strut 75 includes a rectangular-shaped filament 79 with dimensions 78 of about 0.003 inches by 0.005 inches, and made of stainless steel. Filament 79 is formed in a undulating pattern with a primary length 76, a secondary length 57, a first width 71, and a second width 72. In one embodiment, primary length 76 is about 0.020 inches and secondary length 77 is about 0.014 inches. First 71 and second 72 widths are about 0.006 inches and 0.009 inches, respectively. It will be appreciated by those skilled in the art that the pressure at which strut 75 expands will depend, in part, on the geometry, thickness and materials of strut 75. For example, in other embodiments, geometry, thickness and materials of strut 75 are adjusted so that strut 75 expands at between two (2) and ten (10) ATM. It should be appreciated by one skilled in the art that other expansion presures are also possible. Fig. 4B illustrates an embodiment of a structure portion 70 formed by combining a number of the struts 75.

It should be appreciated that the geometries illustrated in Figs. 2A through 4A are relative to each other. Thus, for example, if the geometry, thickness and/or materials of strut 55 are adjusted such that strut 55 expands at about eight (8) ATM, a similar adjustment of struts 65 and 75 would yield expansion pressures of about six (6) ATM and about ten (10) ATM, respectively.

In an embodiment of strut 10, proximal portion 22 and distal portion 24 are formed of struts 55 interconnected as in structure portion 50. Midsection 20 is formed of struts 65 interconnected as in structure portion 60. Since struts 65 expand when subjected to a first pressure (*e.g.*, 3 ATM) and struts 55 expand under a greater second pressure

(*e.g.*, 4 ATM) midsection 20 will expand before proximal 22 and distal 24 portions when stent 10 is subjected to a steadily increasing pressure. Alternatively, expansion pressure is increased by a step-function or other pattern.

At both proximal interface 87 and distal interface 86, struts 55 are interconnected with struts 65. Referring to Fig. 5, an embodiment of proximal interface 87 is illustrated in greater detail. A structure portion 80 includes a portion 82 of midsection 20 and a portion 84 of proximal portion 22 joined at proximal interface 87. Portion 82 of midsection 20 is formed of struts 65 while portion 84 of proximal portion 22 is formed of struts 55.

A method of operating stent 10 is further described in relation to Figs. 6 and 7. Referring to Fig. 6, stent 10 is shown in a partially deployed orientation. Stent 10 includes midsection 20 which expands at a lower pressure than either proximal portion 22 or distal portion 24. Partial deployment involves, in one embodiment, partially inflating balloon 30. As balloon 30 is inflated, it exerts pressure on the inner wall of stent 10 at midsection 20, proximal portion 22, and distal portion 24. Because midsection 20 expands at a lower pressure than either proximal portion 22 or distal portion 24, midsection 20 expands more fully and/or more rapidly. Thus, a cross-sectional area of midsection 20 is greater than a cross-sectional area of either proximal portion 22 or distal portion 24 when stent 10 is partially expanded.

Stent 10 is shown fully deployed in Fig. 7. Full deployment occurs when balloon 30 is inflated so that the pressure on the inner wall of stent 10 is greater than or equal to the pressure required to expand proximal portion 22 and distal portion 24. At this pressure, proximal portion 22 and distal portion 24 fully expand. Upon full expansion, in one embodiment, the cross-sectional areas of midsection 20, proximal portion 22 and the distal portion 24 are generally equal and cylindrical.

In alternative embodiments, stent 10 can be formed with any combination of struts to achieve a desired expansion sequence. For example, in one embodiment, stent 10 is formed using struts 75 at midsection 20 and struts 65 at proximal portion 22 and distal portion 24. Thus, during deployment, proximal portion 22 and distal portion 24 will expand more rapidly than midsection 20.

In one embodiment, stent 10 has two portions, with a two step expansion used to fully expand the two portions. In yet another embodiment, stent 10 is formed using struts 75 for distal portion 24, struts 65 for proximal portion 22, and struts 55 for midsection 20. Thus, during deployment midsection 20 will expand slower than either

proximal portion 22 or distal portion 24. Additionally, distal portion 24 will expand more rapidly than proximal portion 22.

From the preceding description, it should be appreciated that most any expansion sequence can be provided according to the present invention. Further, it should be appreciated that stent 10 can comprise any number of expansion sections, including fewer or a greater number of stent portions than depicted in Figs. 1-7.

For example, Fig. 8 illustrates stent 10 comprising twenty expansion sections 125 individually delineated as sections 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120. Expansion sections 125 can be formed using different geometries and/ or different materials to create a variety of expansion sequences.

In one embodiment, expansion sections 125 are designed to deploy at different pressures such that stent 10 expands first at section 101, then 102, then 103, and continue in order until stent 10 is fully deployed. In an alternate embodiment, stent 10 is designed to deploy first at section 120, then 119, then 118, and continue in order until stent 10 is fully deployed. In yet another embodiment, stent 10 can be designed such that section 110 expands, then sections 109 and 111 expand simultaneously, then sections 108 and 112 expand simultaneously, and continue in that pattern until stent 10 is fully deployed. Those skilled in the art will appreciate that other expansion patterns also fall within the scope of the present invention.

As shown in Fig. 9, stent 10 may be conveniently included as part of a kit 140. Kit 140 includes instructions for use 142 which set forth various procedures for deploying stent 10 using any of the techniques previously described. Instructions for use may be in written or machine readable form. In a preferred embodiment, kit 140 comprises stent 10 crimped over balloon 30 (not shown). Further, it will be appreciated that kit 140 may alternatively include any of the other elements described herein, such as other devices for exerting desired pressure on expandable stent 10, stent delivery apparatus and catheters, including the proximal hub thereof. Further, instructions 142 may describe use of any of the other elements.

The invention has now been described in detail for purposes of clarity of understanding. However, it will be appreciated that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A stent for placement in a body lumen, the stent comprising:

an expandable tubular wall having a first portion and a second portion, the the tubular wall having a side hole therethrough;

the first portion having a first makeup and the second portion having a second makeup, wherein an expansion factor of the first makeup is different from an expansion factor of the second makeup.

2. The stent of claim 1 wherein the first makeup and the second makeup provide the expandable tubular wall with a predetermined sequence of expansion.

3. The stent of claim 1 wherein the expansion factor of the first makeup includes an expansion rate at a particular pressure.

4. The stent of claim 1 wherein the first makeup is a material formed in a first geometry and the second makeup is the material formed in a second geometry.

5. The stent of claim 4 wherein the first geometry expands in response to a first pressure and the second geometry expands in response to a second pressure, the second pressure being greater than the first pressure.

6. The stent of claim 1 wherein the first portion is adapted to expand at a faster rate than the second portion.

7. The stent of claim 1 further comprising an expander at least partially disposed within an area defined by the expandable tubular wall.

8. The stent of claim 7 wherein the expander is operable to apply pressure on the expandable tubular wall.

9. The stent of claim 7 wherein the expander is a balloon.

10. The stent of claim 1 wherein the expandable tubular wall has a longitudinal axis extending therethrough, the first portion located at a first position along the axis and the second portion located at a second position along the axis.

11. The stent of claim 10 wherein the expandable tubular wall is generally cylindrical when expanded.

12. The stent of claim 1 wherein the expandable tubular wall further comprises a third portion adjacent to the first portion and apart from the second portion, the third portion having the second makeup, wherein the second and third portions have about the same expansion factor.

13. The stent of claim 12 wherein the first portion expands more rapidly than the second and third portions when the first, second and third portions are subjected to a steadily increasing pressure.

14. A stent as in claim 1 having a plurality of portions including said first and second portions, wherein at least some of said plurality of portions have a different makeup to expand in response to a different pressure.

15. A method for deploying a stent in a body lumen, the method comprising:

providing a stent comprising a tubular wall having a first portion and a second portion, the first portion adapted to expand in response to a first pressure and the second portion adapted to expand in response to a second pressure;

positioning the stent in the body lumen;

subjecting the tubular wall to a first pressure wherein the first portion expands more than the second portion in response to said first pressure; and

subjecting the tubular wall to a second pressure greater than said first pressure, said second pressure operating to fully expand said stent tubular wall.

16. The method of claim 15, wherein the second pressure causes the tubular wall to be generally cylindrical.

17. The method of claim 15, wherein the first portion of the tubular wall includes a side hole.

18. The method of claim 17, wherein said positioning the stent comprises positioning the side hole adjacent to a bifurcation in the body lumen.

19. The method of claim 15 wherein said positioning the stent comprises positioning the first portion adjacent to a critical portion of the body lumen.

20. The method of claim 15 further comprising providing an expander, said expander adapted for subjecting said tubular wall to a desired pressure.

21. The method of claim 20 wherein the expander is a balloon.

22. The method of claim 21 wherein said subjecting said tubular wall to said first pressure comprises inflating the balloon.

23. The method of claim 22 wherein said subjecting said tubular wall to said second pressure comprises further inflating the balloon.

24. A kit comprising:

a stent as set forth in claim 1; and

instructions setting forth a method for deploying the stent in a predetermined sequence of expansion.

FIG. 1

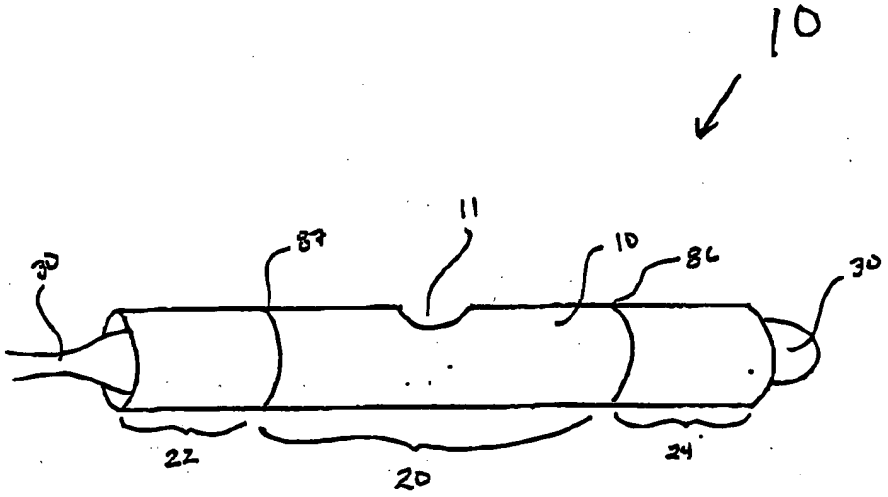


FIG 2B

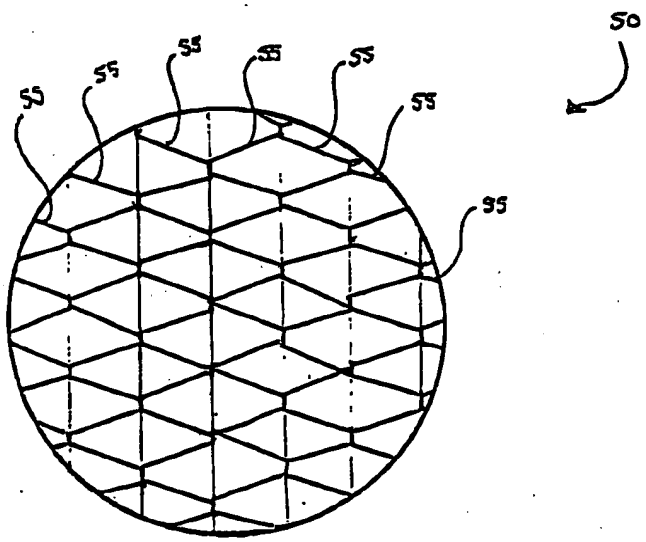


Fig 3.

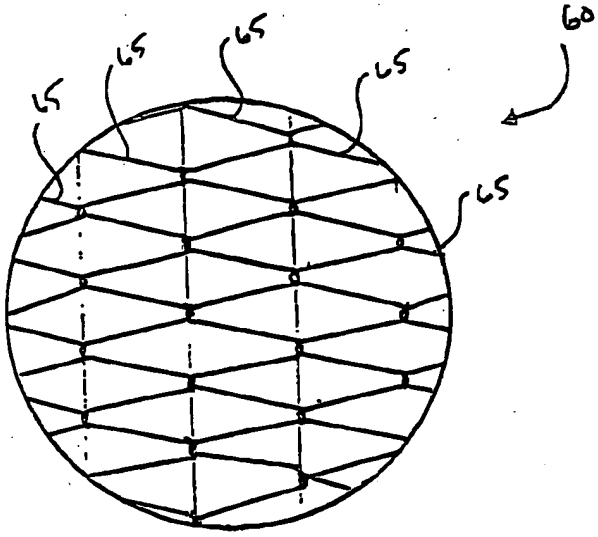


Fig 4.

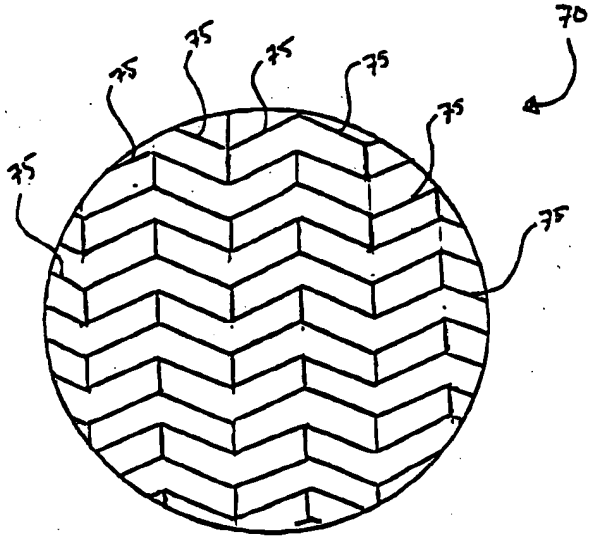


FIG 3A

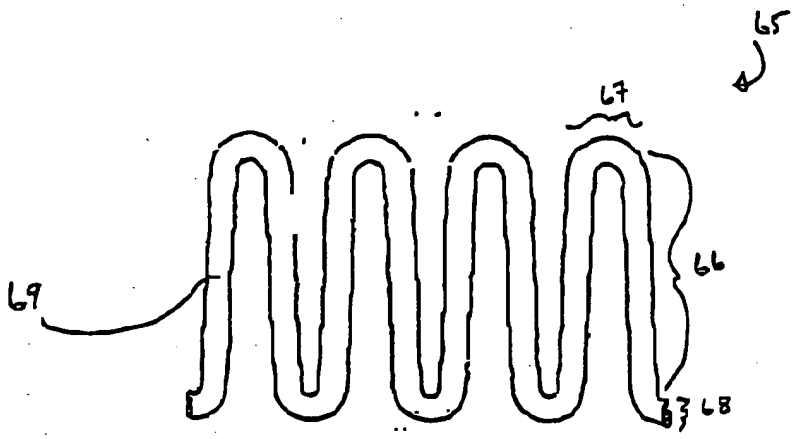


FIG 2A

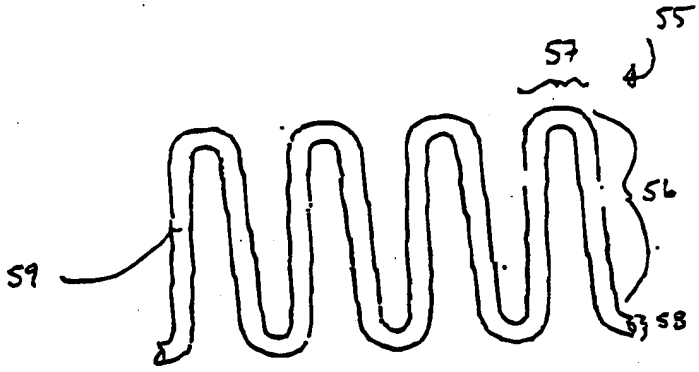


FIG 4A

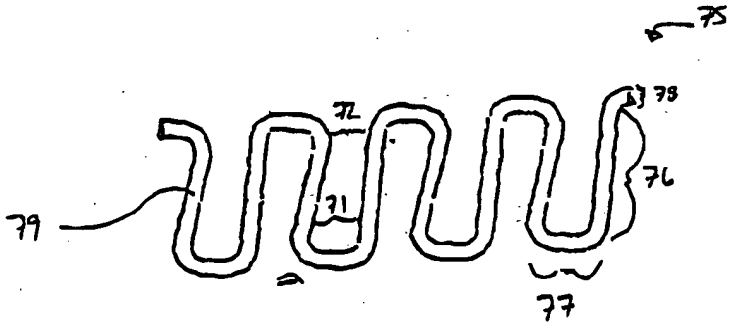


Fig 5

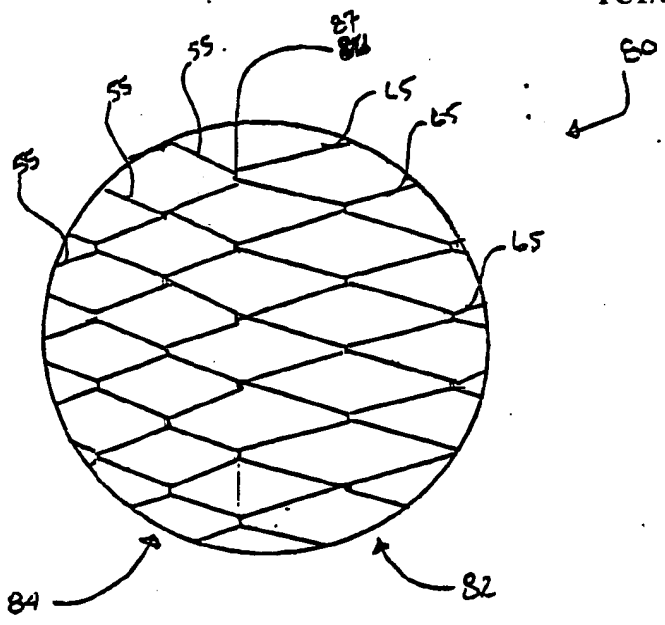


Fig 6

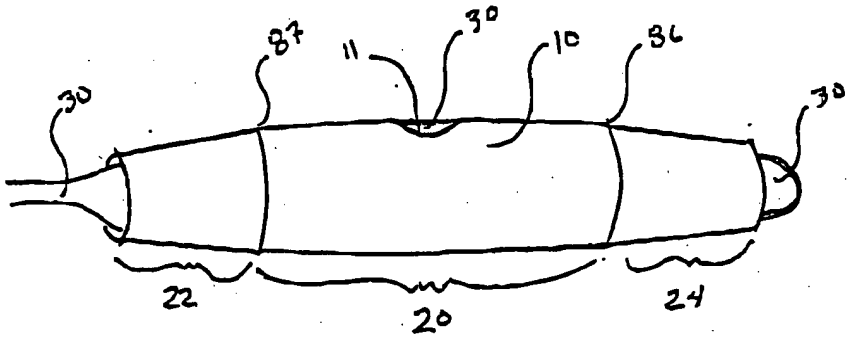
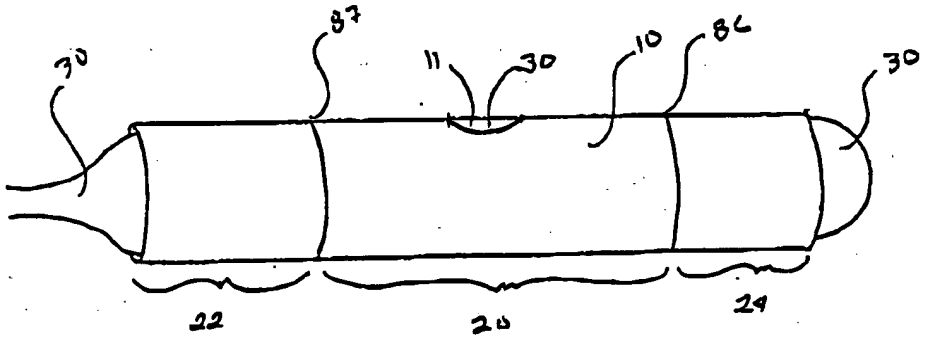


Fig 7



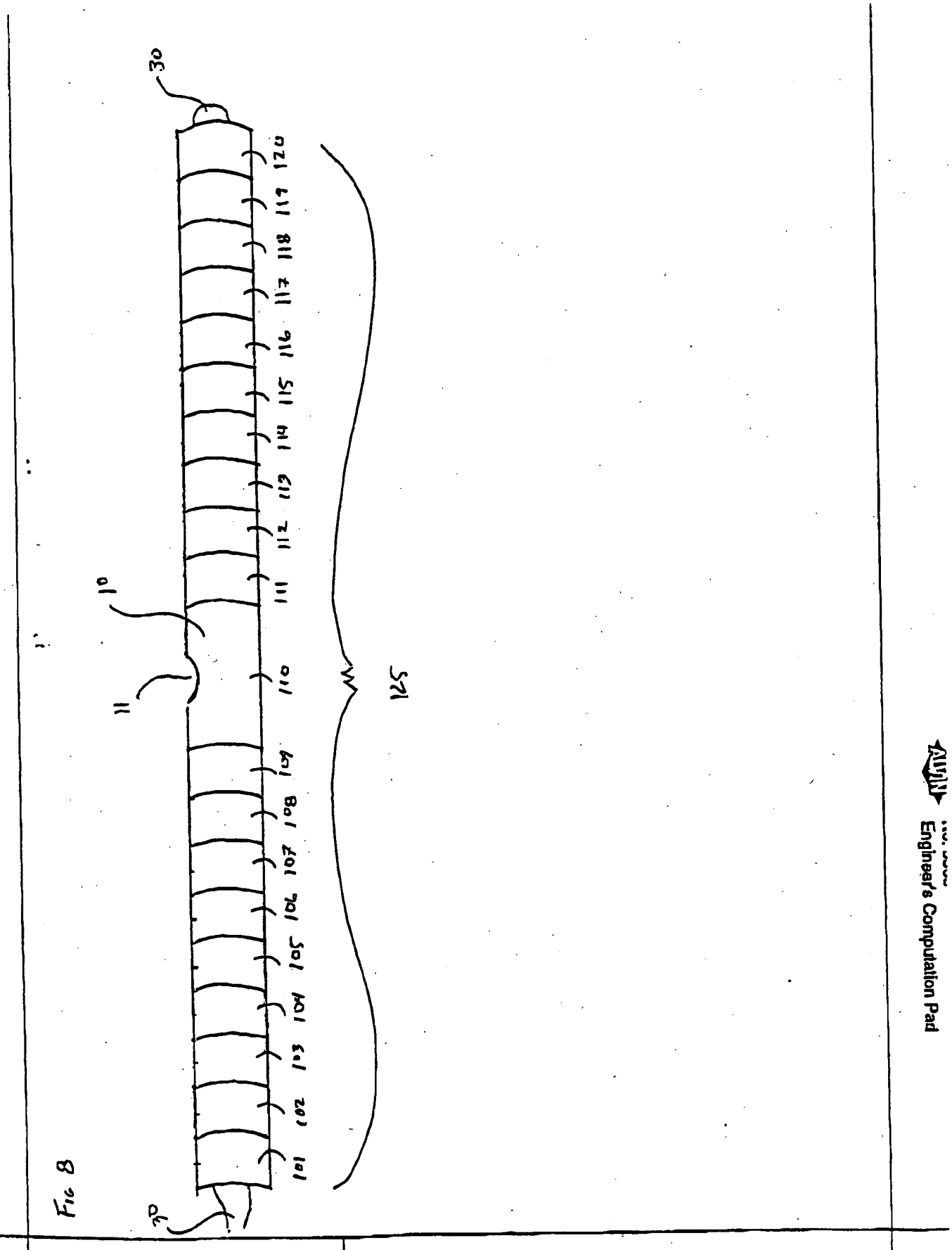
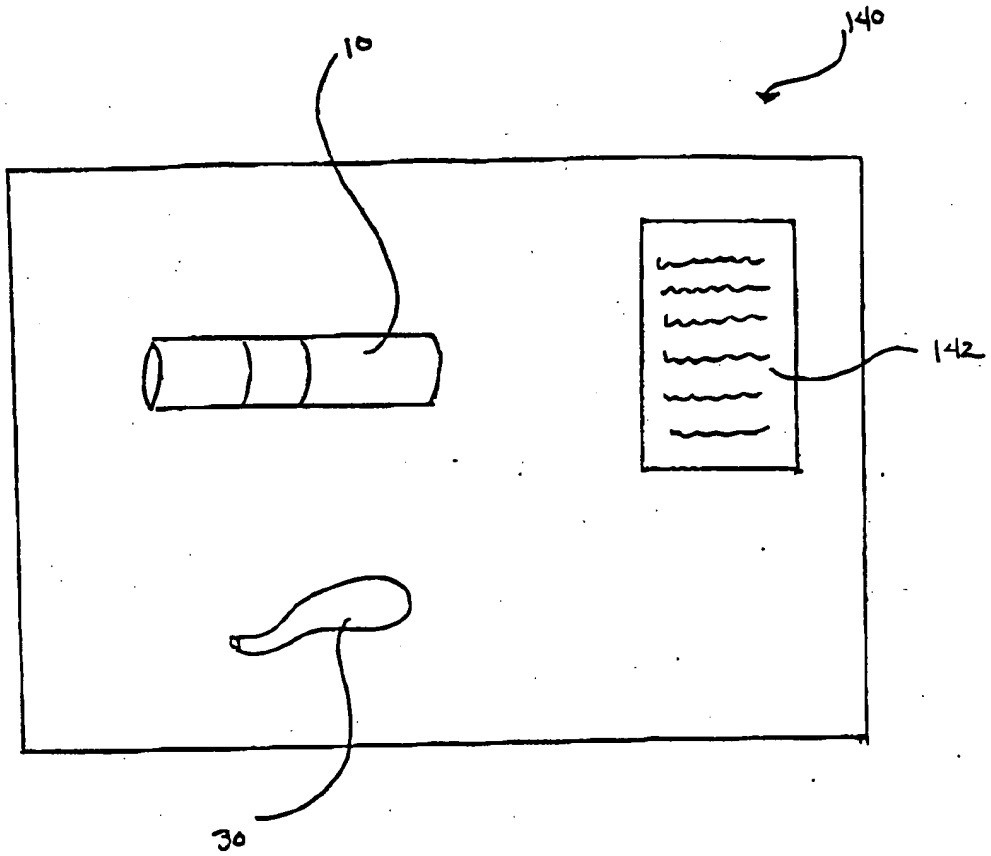


Fig 8

Fig 9



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/26378

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06
US CL :606/191, 195, 198; 623/1.13, 1.15, 1.16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/191, 195, 198; 623/1.13, 1.15, 1.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,449,382 A (DAYTON) 12 September 1995, entire document.	1-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search 09 NOVEMBER 2000	Date of mailing of the international search report 28 NOV 2000
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